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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,566	07/26/2002	Priya Gopinath	124320	3231

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CANTOR COLBURN, LLP
55 GRIFFIN ROAD SOUTH
BLOOMFIELD, CT 06002

EXAMINER	
LAVIN, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
2621	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/064,566	GOPINATH ET AL.	
	Examiner	Art Unit	
	Christopher L. Lavin	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/26/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

105 Requirement for Information

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. The information is required to extend the domain of search for prior art. Limited amounts of art related to the claimed subject matter are available within the Office, as it appears much of this material is well known in the art and has not been patented (see Hong for example). It appears that the majority of the art for this case has been released in various medical journals. A broader range of art to search is necessary to establish the level of knowledge of those of ordinary skill in the claimed subject matter art of CT Calibration using Phantoms and Mass Scoring.

3. In response to this requirement, please provide copies of each publication which any of the applicants authored or co-authored and which describe the disclosed subject matters of CT Calibration using Phantoms and Mass Scoring.

4. In response to this requirement, please provide the title, citation and copy of each publication that is a source used for the description of the prior art in the disclosure. For each publication, please provide a concise explanation of that publication's contribution to the description of the prior art.

5. In response to this requirement, please provide the title, citation and copy of each publication that any of the applicants relied upon to develop the disclosed subject matter that describes the applicant's invention, particularly as to developing CT Calibration

using Phantoms and Mass Scoring. For each publication, please provide a concise explanation of the reliance placed on that publication in the development of the disclosed subject matter.

6. In response to this requirement, please provide the title, citation and copy of each publication that any of the applicants relied upon to draft the claimed subject matter. For each publication, please provide a concise explanation of the reliance placed on that publication in distinguishing the claimed subject matter from the prior art.

7. In response to this requirement, please state whether any search of prior art was performed. If a search was performed, please state the citation for each prior art collection searched. If any art retrieved from the search was considered material to demonstrating the knowledge of a person having ordinary skill in the art to the disclosed invention, please provide the citation for each piece of art considered and a copy of the art.

8. In response to this requirement, please state the specific improvements of the subject matter in claims 1 – 25 over the disclosed prior art and indicate the specific elements in the claimed subject matter that provide those improvements. For those claims expressed as means or steps plus function, please provide the specific page and line numbers within the disclosure which describe the claimed structure and acts.

9. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in

the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

10. The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

11. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

12. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1 – 5, 8, 9, and 15 – 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Hong ("Coronary Artery Calcium: Absolute Quantification in Nonenhanced and Contrast-enhanced Multi-Detector Row CT Studies", Radiology, volume 223, pages 474-480, May 2002).

In regards to claim 1, A method for calculating mass scores of calcium deposits, the method comprising: obtaining patient image data (Page 476, col. 2, Image Acquistion); identifying calcium plaque in said patient image data, wherein said calcium plaque is associated with a plurality of discrete patient pixel elements and wherein each of said patient pixel elements includes a patient pixel value expressed in Hounsfield units (Page 476, col. 2, Measurements of Coronary Calcium); converting said patient pixel values into patient density values using a calibration curve equation (Page 476, col. 2, Measurements of Coronary Calcium, Figure 2); and outputting said patient density values (Page 476, col. 3, Results).

In regards to claim 2, The method of claim 1 wherein said obtaining patient image data includes obtaining patient image data using a computed tomography imaging system (Page 476, col. 2, Image Acquisition).

In regards to claim 3, The method of claim 1 further comprising: summing said patient density values resulting in a total mass score; and outputting said total mass score (Page 476, col. 2, Measurements of Coronary Calcium; Figure 4).

In regards to claim 4, The method of claim 3 wherein said total mass score includes said patient density values for one vessel within a heart (Page 476, col. 2, Measurements of Coronary Calcium; Figure 3: Clearly Total Mass is found by finding the Mass in each vessel and then combing the information.).

In regards to claim 5, The method of claim 3 wherein said total mass score includes said patient density values for all vessels within a heart (Page 476, col. 2, Measurements of Coronary Calcium; Figure 4).

In regards to claim 8, The method of claim 1 wherein said calibration curve equation is precomputed (page 477, col. 3, first partial paragraph, Figure 2).

In regards to claim 9, The method of claim 1 further comprising precomputing said calibration curve equation, wherein said precomputing includes: obtaining phantom image data associated with a plurality of discrete phantom pixel elements corresponding to a calcium insert of known density in a phantom, wherein each of said phantom pixel elements includes a phantom pixel value expressed in Hounsfield units (Page 475, col. 3, Phantom Study); graphing said phantom image data against said known density of said calcium insert (Figure 2); and developing said calibration curve equation for computing said patient density values in response to said patient pixel values (page 477, col. 3, first partial paragraph, Figure 2).

In regards to claim 15, The method of claim 9 wherein said phantom is an anthropomorphic cardiac phantom body including calcium inserts of known density (Page 475, col. 3, Phantom Study).

In regards to claim 16, claim 16 is rejected for the same reasons as claim 9. The argument analogous to that presented above for claim 9 is applicable to claim 16.

In regards to claim 17, claim 17 is the system claim of claim 1. Therefore only the actual parts claimed will be discussed here. The imaging system is a CT device, the object is a patient or phantom, and the processing device is an Insight workstation.

In regards to claim 18, The system of claim 17 wherein said object is a patient (page 476, col. 1, Patient Population).

In regards to claim 19, The system of claim 17 wherein said imaging system is a computed tomography imaging system (Page 476, col. 2, Image Acquisition).

In regards to claim 20, The system of claim 17 wherein said imaging system and said processing device are physically located in the same geographic location (page 476,col. 2, Measurements of Coronary Calcium: The Insight workstation is a standard windows computer and therefore can be connected either directly to the CT machine or remotely using a network.).

In regards to claim 21, The system of claim 17 wherein said imaging system and said processing device are physically located in different geographic locations (page 476,col. 2, Measurements of Coronary Calcium: The Insight workstation is a standard windows computer and therefore can be connected either directly to the CT machine or remotely using a network.).

In regards to claim 22, The system of claim 17 wherein said processing device is in communication with said imaging system over a network (page 476,col. 2, Measurements of Coronary Calcium: The Insight workstation is a standard windows

computer and therefore can be connected either directly to the CT machine or remotely using a network.).

In regards to claim 23, The system of claim 22 wherein said network is the Internet (Official Notice is taken that it is well known that the Internet is a network that can be used to transfer data between computers. Therefore it would have been obvious to connect the Insight workstation remotely to the CT machine using the Internet as this would allow for cost savings as every CT machine would not need its own workstation).

In regards to claim 24, claim 24 is rejected for the same reasons as claim 1. The argument analogous to that presented above for claim 1 is applicable to claim 24.

In regards to claim 25, claim 25 is rejected for the same reasons as claim 16. The argument analogous to that presented above for claim 16 is applicable to claim 25.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong in view of Arnold (4,922,915).

In regards to claim 6, Hong discloses (476, col. 3, Measurements of Coronary Calcium) that the mass score is automatically computed. Hong also discloses using thresholds for this process (for example Figure 2). Finally in Figure 3 Hong highlights calcifications. Hong does not disclose a manual operation. However every automatic operation in the medical field still has some manual intervention if nothing else.

Arnold teaches (col. 12, lines 28 – 52) that an operator can manually assist a program before it automatically segments a medical image.

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to allow a users manual input (as taught by Arnold) in the method disclosed by Hong. By allowing a user to manually start a process such as automatic segmenting the final segmentation will be more accurate with the seed information provided by the user.

In regards to claim 7, The method of claim 6 wherein said preselected threshold criteria includes patient pixel elements with patient pixel values measuring 130 Hounsfield units or greater (page 476, col. 2, Measurement of Coronary Calcium).

19. Claims 10 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong in view of Arnold and Feldman.

In regards to claims 10 – 14, Hong as previously shown discloses using an anthropomorphic phantom. Hong does not disclose using two separate phantoms. However this concept is well known in the art.

Feldman discloses (col. 5, lines 36 – 47 and lines 58 – 63, Figure 4) that a poly phantom, of differing sizes, and a calibration phantom can be used to calibrate a system. Feldman alone covers claims 10 – 12; however, as claims 13 – 14 include calcium inserts Arnold has been provided to teach this concept. Feldman's calibration phantom does not consist of calcium rods. Arnold teaches (col. 9, line 60 – col. 10, line 9) that a calibration phantom containing 5 calcium rods can be created 3 of these rods measuring 50, 100, and 200 mg/cc.

Therefore it would have been obvious to one having ordinary skill in the art at the item of the invention to the replace the phantom disclosed by Hong with two phantoms (as taught by Feldman). The calibration phantom could be provided by Arnold as it closely mirrors the calibration standard disclosed in Hong. By using two separate phantoms the CT machine can be more easily calibrated for people of different sizes without requiring multiple anthropomorphic phantoms, which are far more expensive than a poly phantom, which can have its sized change simply by adding or removing

water. Thus by using the calibration phantom of Arnold and the poly phantom of Feldman instead of the phantom of Arnold a cost savings can be obtained without a significant decrease in calibration resolution.

Conclusion

20. This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Lavin whose telephone number is 571-272-7392. The examiner can normally be reached on M - F (8:30 - 5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mancuso Joseph can be reached on (571) 272-7695. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Lavin

BRIAN WERNER
PRIMARY EXAMINER